

In the United States Court of Federal Claims

No. 99-212V
(Filed: January 16, 2009)

JOHN DOE/11 and JANE DOE/11,
as representatives of the Estate of
CHILD/DOE/11, Deceased.

Petitioners,

v.

SECRETARY OF THE DEPT. OF
HEALTH AND HUMAN SERVICES,

Respondent.

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ORDER

Upon review of the record on Petitioners' Motion for Review of the Special Master's Decision on Remand, the Court requests that the parties, in addition to proffering their arguments, address the following issues during the upcoming oral argument:

1. What does the record evidence indicate an average brain weight to be for an infant of Doe's age, and what are the applicable standard deviations?
2. Does a brain have to be significantly heavy to show the edema in question or only somewhat heavy? Statistically, what would constitute "significantly?" How much heavier than one standard deviation from the mean must the brain weight be before it is considered "heavy," or markedly edematous? In Perez v. Sec'y of HHS, 2008 WL 763301, at *34 (Fed. Cl. Spec. Mstr. Mar. 4, 2008), the Special Master concluded: "549 grams actual postmortem measured brain weight is significantly greater than the norm of 523 grams... it appears that Mario's brain was significantly heavier than normal."
3. If the child's brain was within two standard deviations of the mean, or within 95 percent of the population in weight, would we consider her to have an unusually heavy brain? How is this

answer affected by her body weight and length and organ weight?

4. To what extent did the Special Master's conclusions on brain weight rely on Respondent's Exh. LL – a study that included edematous brains?

5. The Special Master seems to suggest that this brain may have experienced an increase in weight between death and autopsy. See Decision on Remand at 23-24. Were the brains in the various brain weight studies all subject to the same increase in weight at autopsy?

6. Must the symptoms of a cytokine storm (See Decision on Remand at 33-40) necessarily precede death in the case of a young baby like this one? Dr. McCusker testified that a progression of symptoms would have taken hours. See Tr. at 258. To what extent does this opinion depend on the study she cites that involved healthy adults? See Tr. at 254. What other evidence supports this opinion? See also Sword v. Sec'y of HHS, 1998 WL 957201 (Fed. Cl. Spec. Mstr. Dec. 29, 1998) (“When someone does not live long enough to satisfy the interpretive aid of having encephalopathy for at least six hours, the undersigned will not hold that that vaccinee is precluded from prevailing...”).

7. What impact does the limited pediatric experience of Petitioners' experts (See Decision on Remand at 12) have in assessing brain weights? Why did the Special Master deem Respondent's experts more authoritative on this subject? What degree of deference does this Court owe the Special Master's credibility determinations on expert witnesses? Did all of the expert witnesses testify via telephone or video conference? If so, does this affect the credibility assessment?

8. What is the effect of the Federal Circuit's decision in De Bazan v. Sec'y of HHS, 539 F.3d 1347 (Fed. Cir. 2008)? To what extent does De Bazan permit the Special Master to consider SIDS for the “limited purpose” of determining causation in fact? See Decision on Remand at 28-33.

s/Mary Ellen Coster Williams
MARY ELLEN COSTER WILLIAMS
Judge